

Snow Control 2.0 - web-based interventions for the reduction of cocaine use

Submission date 18/02/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 24/02/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/09/2019	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Web-based self-help programs that stop people from taking problematic substances (such as cocaine) are able to reach “hidden” consumer groups in the general population who often fear stigmatisation. These programs place few demands on participants, offering services without attempting to control their behaviours by “force”. The benefits of these programs often significantly outweigh their costs, which is of interest for both low-income and high-income industrialised countries. In Western European countries, including Switzerland, cocaine is the most widely used psychoactive (mind altering) substance after alcohol, tobacco and cannabis. Although approximately one in ten users develop serious problems of dependency, only a minority attends outpatient addiction counselling centres. The objective of this study is to test how well a web-based self-help intervention performs in combination with, or independent of, guided chat therapy compared to a waiting list control condition in helping people reduce or stop their use of cocaine. Our intervention will be based on the principles of motivational interviewing, self-control practices, and methods of cognitive behavioural therapy. We hope to gain substantial knowledge for designing effective guided and unguided Internet based treatment for problematic cocaine users.

Who can participate?

Adults (aged at least 18) that have used cocaine on more than two occasions in the last 30 days.

What does the study involve?

Participants are randomly allocated into one of three groups. Those in group 1 are given access to the web-based self-help program and are given three individual chat-counseling sessions based on motivational interviewing (MI) and Cognitive Behavioural Therapy (CBT) approaches that are tailored to the data the participants entered into the self-help program, the exploration and improvement of current social support and relationships unrelated to cocaine use and individual requests. Participants in group 2 are given access to the web-based self-help program which is based on classical CBT, approaches for the treatment of cocaine dependence, MI approaches, behavioural stress management (BSM) and CBT depression therapy. Participants in group 3 are assigned to the control group and are placed on a waiting list to receive the treatments after the study is complete.

What are the possible benefits and risks of participating?

There are only minimal risks associated with participation such as slight withdrawal symptoms and participants have to be aware that web-based interventions cannot replace face-to-face treatment of problematic cocaine use. The benefits of participation are the free and anonymous treatment access and the physical and mental health benefits that can result from the reduction /cessation of cocaine use.

Where is the study run from?

Swiss Research Institute for Public Health and Addiction (Switzerland)

When is the study starting and how long is it expected to run for?

March 2015 to August 2017

Who is funding the study?

Swiss National Science Foundation (Switzerland)

Who is the main contact?

Dr Michael Schaub

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Snow Control 2.0 - the effects of chat-counseling and web-based self-help, web-based self-help alone and a waiting list control program on cocaine use in problematic cocaine users: a randomized controlled trial

Acronym

Snow Control 2.0

Study objectives

We hypothesize that web-based interventions, which are more interactive, will be more effective in reducing cocaine use among problematic cocaine users. We will test the following detailed study hypotheses with respect to the main outcome, i.e., reduction of the quantity of cocaine used between the baseline and the 6-month follow-up:

1. Tailored chat-based therapy in combination with web-based self-help for the reduction of cocaine use (study arm 1) is more effective than the waiting list control condition (study arm 3).
2. Web-based self-help for the reduction of cocaine use (study arm 2) is more effective than the waiting list control condition (study arm 3).
3. Chat-based therapy in addition to web-based self-help for the reduction of cocaine use (study arm 1) is more effective than web-based self-help alone (study arm 2) in reducing cocaine use.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics committee of the Canton of Zurich, 02/02/2015, ref: KEK-ZH-No. 2014-0611

Study design

This is an Internet-based interventional three-arm randomized controlled trial.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Internet/virtual

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Problematic cocaine use.

Interventions

Study interventions:

The intervention in the first arm consists of the web-based self-help intervention from study arm two in combination with three individual chat-counseling sessions based on MI and CBT

approaches that are tailored to the data the participants entered into the self-help intervention, the exploration and improvement of current social support and relationships unrelated to cocaine use and individual requests. The web-based self-help intervention from study arm two is based on classical CBT, approaches for the treatment of cocaine dependence, MI approaches, BSM and CBT depression therapy. Study arm three consists of a classical waiting list.

Intervention modules:

The following modules, organized into two main parts, are offered as a web-based self-help intervention (study arms one and two) and accessible after successful registration and completion of baseline assessment. Part 1 has to be worked through systematically. Part 2 is presented in a clearly arranged menu and its modules are freely accessible as soon as part 1 is completed and recommended to be worked through in the order presented below in case there are no urgent personal reasons to jump to a specific module such as present strong craving etc. Corresponding participants are also recommended to repeat the modules as needed.

1. Part 1: Introduction

1.1. Registration process

1.2. Personal companion (introduction of 6 companion profiles and personal choice of own companion)

1.3. Examination of the pros and cons resulting from a change in cocaine consumption patterns to address motivation

1.4. Goal setting and explanation of the e-mail reminders

1.5. Explanation of the cocaine consumption diary and its fully automated progress charts and statistics

1.6. Explanation of the "My Snow Control" folder (This folder allows individuals to review the acquired summarised module documents, e.g., the list of the top five strategies for dealing with cocaine cravings)

1.7. Explanation of the emergency button for immediate responses to frequently asked questions and access to emergency contacts

2. Part 2: Modules

2.1. Module 1: Strategies for goal achievement

2.2. Module 2: Identifying your risk situations

2.3. Module 3: Carrying about your needs: reduction of stress and depression symptoms, sleep hygiene

2.4. Module 4: Dealing with cocaine craving

2.5. Module 5: Dealing with relapses

2.6. Module 6: Six step program to tackle your problems

2.7. Module 7: Saying "no" to foster refusal skills

2.8. Module 8: Preserving achievements

Furthermore, a glossary that explains the terms, definitions and concepts used in the intervention, information about the history of cocaine use, the short-, medium- and long-term effects of cocaine, the physical risks of cocaine (addiction, cardio-vascular, etc.), co-occurring mental health problems (depression, psychosis, ADHD, etc.), is planned to be provided in an appendix accessible after registration, along with frequently asked questions and their corresponding answers.

Personal companion:

During the introduction, six possible companions will be introduced briefly. They vary between gender, age, sexual orientation and family and professional situation in order to provide a maximum of identification. According to this choice, in every module the personal companion optionally provides a specific advice or example. However, there is the possibility to change the

personal companion or simply go through the advices and examples provided by the other companions.

Goal setting and motivational e-mail feedback:

To prevent participants in study arm one and two from setting their consumption goal too low and thus quitting the intervention within the first weeks as it occurred frequently in the preliminary Snow Control study or from setting their goals too high and risking early relapse, additional tailored motivational advice will be developed and implemented. Participants will be recommended to set their overall six-week goal in the beginning and will be recommended a minimal reduction of 40% of their weekly used cocaine quantity. In a second step, tailored weekly instructions will be provided that stimulate a successive weekly reduction of 20-30% in the first three weeks and motivate to try again with a lower aim (e.g. 15-20%) of reduction in case the previous aim has not been reached. Those participants who seek cocaine abstinence will also be encouraged to make similar step-by-step reductions until full abstinence has been reached. The maintenance of abstinence from one day to the next, as is recommended by the content of tobacco prevention websites for smoking cessation, will not be advised for safety reasons (e.g. to avoid possible severe withdrawal symptoms). In case participants reach their weekly aims, positive feedback will be presented and participants will be encouraged to go in a similar way in order to reach or even outperform their overall goal. Once a participant has reached his or her overall goal he or she will be encouraged to maintain their consumption as it is or to choose to reduce successively further until week 6. Moreover, weekly motivational E-Mail reminder feedback tailored to the weeks passed since the intervention start and the module progress are planned to be implemented. Moreover, a substantial number of alternating short motivational hints will be developed and implemented for every module page in order to increase motivation and alteration.

Extensions in the chat condition:

Chat contacts will be provided in addition to the self-help part in study arm 1 and aim in particular also on the reinstatement of social reward discussed in recent findings that is assumed to be limited in the self-help only study arm (study arm 2) without sensitising personal therapist contacts.

Three additional chat therapy sessions (study arm 1 only) will apply support regarding behavioural change according to MI, discuss the modules of the web-based self-help part based on MI and CBT, review the development of the consumption diary, and foster and review social rewarding contacts. The chat sessions will be structured as follows:

3. Chat session 1: Starting point and objective agreement

3.1. Personalized feedback according to baseline assessment and potential cocaine related physical and mental health risks

3.2. Review of successful strategies of change related to topics other than cocaine

3.3 Imagining daily routines after cocaine cessation; exploration of aims to live without, and the dissonances of cocaine use; mobilization of social support with the invitation for a relevant third person to join chat session 2

3.4 Review and agreement on the overall cocaine use objective

3.5. Review strategies to deal with cocaine craving and perspective for the second chat session

4. Chat session 2: Experience exchange, social support and relationships

4.1. Experience exchange regarding the agreed-upon objective since the starting point

4.2. Review of the patterns of the consumption diary goals and achievements

4.3. Review and consolidation of web-based self-help modules

4.4. Review of social rewards before the start of cocaine use

4.5. Experience and improvement of current social support and relationships

4.6. Revising intervention objectives and perspective for the third chat session

5. Chat session 3: Review and consolidation

- 5.1. Experience exchange regarding the agreed-upon objective since the starting point
- 5.2. Review of the patterns of the consumption diary goals and achievements
- 5.3. Consolidation of web-based self-help modules, identifying the best five strategies for long-term success
- 5.4. Experience possible change and improvement of social support and relationships
- 5.5. Defining long-term objectives and saving strategies for long-term success

Health care professionals will be assigned the role of online therapists who contact registered users during their 6 weeks program to appoint two dates for a chat session in writing. To provide a convenient handling of clients, therapists will have access to a specific user management area, where they can add appointed chat dates, define current status, add personal comments about their clients, inspect client's progress in consumption in clearly arranged charts as well as their module progress, look up previous chat histories and so on. Specific lists will help each therapist to keep track of users, e.g. a list with "all users", "my clients" or "my upcoming chat sessions". All dialogs in written form from all chat sessions will be recorded in a database for further analysis.

Waiting list condition:

Participants randomized to the waiting list will have the opportunity to participate in the web-based self-help intervention 6 month after registration. Follow-up measures for those participants will be assessed online or by telephone interviews for those participants who cannot be reached online at the 6 month follow-up.

Technical specifications:

The Snow Control 2.0 front-end structure and design is built with XHTML, Cascading Style Sheets (CSS; a style sheet language used to describe the presentation semantics of a document written in a markup language), JavaScript, and AJAX (a group of interrelated web development methods used on the client-side to create interactive web applications). The back-end is built with a content management system (CMS) and Modules. All User data is planned to be stored in a relational database management system MySQL on password-protected servers in Switzerland. At registration, it is mandatory to define a unique username and password to protect personal consumption and health details. Moreover, users are advised to open a free and anonymous third party email account while indicating personal details. Finally yet importantly, we will optimize the revised snow control self-help version to tablet computers and smart phones in order that those participants who possess these mobile devices can also log in, fill out their consumption diary and complete their modules on the way.

Intervention Type

Behavioural

Primary outcome measure

The weekly quantity of cocaine use expressed in grams in the consumption diary, a measurement that has been shown to be very promising in the first preliminary Snow Control study.

Secondary outcome measures

1. Severity of Dependence Scale (SDS), a 5-item questionnaire that indicates the severity of dependence on cocaine. Each of the five items is scored on a 4-point scale (0-3). The total score is obtained through the addition of the 5 item ratings. High scores indicate a high level of dependency.
2. The weekly number of cocaine use days in the last 30 days
3. The "Fragebogen Substanzanamnese" (FDA) that ascertains the years of lifetime consumption,

the past month's consumption, and the way of consumption for the DSM-IV/ICD-10 substances of abuse. This measure was derived from the EuropeASI.

4. The short version of the Mental Health Inventory (MHI-5) which is a validated and user-friendly self-assessment questionnaire that assesses recent mental distress and self-reported diagnoses of depression.

5. The Social Support Appraisals (SS-A) Scale is a 23 item outcome measure assessed by a four point Likert scale ranging from 1 (strongly agree) to 4 (strongly disagree) that measures subjective appraisal of social support, designed to tap into the extent to which an individual believes that he or she is loved by, esteemed by, and involved with family, friends and others. This measure has been shown to predict relationships with a range of measures of support appraisals, support resources, and psychological distress.

6. The Working Alliance Inventory (WAI-SR) is a 12-item, self-report questionnaire consisting of three subscales designed to assess three primary components of the working alliance.

6.1. How closely client and therapist agree on and are mutually engaged in the goals of treatment

6.2. How closely client and therapist agree on how to reach the treatment goals

6.3. The degree of mutual trust, acceptance, and confidence between client and therapist. The composite score is used as a global measurement of working alliance. Respondents are asked to rate each statement on a 7-point Likert scale ranging from 1 (never) to 7 (always).

7. Client intervention satisfaction will be ascertained with the client satisfaction questionnaire (CSQ-4), a brief user-friendly instrument with good psychometric properties that has been tested in numerous studies on diverse client samples. Intervention retention will be derived from the last cocaine use input entered into the consumption diary in study arms one and two. Finally, self-help intervention participation will be measured by the consumption diary entries, the number of completed modules and the number of logins in the login history in study arm 1 and 2 during the 6 weeks of intervention.

Overall study start date

01/03/2015

Completion date

31/08/2017

Eligibility

Key inclusion criteria

1. Cocaine use > 4 occasions last 30 days
2. Minimal age of 18 years

Participant type(s)

Mixed

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

432

Total final enrolment

416

Key exclusion criteria

1. Participation in other psycho-social or pharmacological treatments for the reduction /cessation of cocaine use
2. Opioid use during last 30 days (exception: substitution maintenance treatment for opioid dependence without heroin use last 30 days)
3. Ever been in treatment for cardiovascular problems or apoplexy

Date of first enrolment

01/03/2015

Date of final enrolment

31/03/2017

Locations

Countries of recruitment

Switzerland

Study participating centre

Swiss Research Institute for Public Health and Addiction

Zurich

Switzerland

8031

Sponsor information

Organisation

Swiss National Science Foundation

Sponsor details

Wildhainweg 3

Postfach 8232

Bern

Switzerland

3001

Sponsor type

Research organisation

Website

<http://www.snf.ch/>

ROR

<https://ror.org/00yjd3n13>

Funder(s)

Funder type

Government

Funder Name

Schweizerische Nationalfonds zur Förderung der Wissenschaftlichen Forschung

Alternative Name(s)

Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, SNF, SNSF, FNS

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Switzerland

Results and Publications

Publication and dissemination plan**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	10/07/2015		Yes	No

[Results article](#)

results

22/05/2019

19/09/2019

Yes

No